UNITED STATES DISTRICT COURT
DISTRICT OF RHODE ISLAND

IN RE LOESTRIN 24 FE ANTITRUST LITIGATION	MDL No. 2472 Master File No. 1:13-md-2472-S-PAS
THIS DOCUMENT RELATES TO: ALL END-PAYOR CLASS ACTIONS	**REDACTED PUBLIC VERSION**

END-PAYOR PLAINTIFFS' COMBINED MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO EXCLUDE THE TESTIMONY AND OPINIONS OF JAMES W. HUGHES, PH.D., AND IN OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE THE TESTIMONY AND OPINIONS OF GARY L. FRENCH, PH.D.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Rules

Other Authorities

I. INTRODUCTION

End-Payor Plaintiffs ("EPPs") submit this memorandum of law in support of their motion to exclude Defendants' class certification expert James Hughes, Ph.D., and in opposition to Defendants' motion to exclude EPPs' expert Gary French, Ph.D. EPPs submit a combined memorandum of law because many of the reasons why Dr. French's opinions should not be excluded parallel the reasons why Dr. Hughes' opinions should be excluded.

The EPPs' expert, Gary French, Ph.D., has conducted a robust analysis of the evidence and data produced in this case. He has designed methodologies for proof of injury and amount of damages on a class wide basis. In doing so, he employs the established methodology of analyzing impact and injury in branded prescription drug monopolization cases. He employs established laws of economics in his analysis. Analyses similar to Dr. French's have been repeatedly accepted by courts to certify class actions, and that same methodology is applicable here.

In contrast, Defendants' *Daubert* attack against Dr. French, and the opinion of their sole expert in the EPP case, Dr. James Hughes, rely upon substantial mischaracterizations of Dr. French's work, EPPs' theories of liability, and EPPs' class definition. Contrary to Defendants' claims, Dr. French has conducted extensive analysis of the structure of the industry, analysis of the data, review of the evidence, and has testified to opinions which "fit" the case and the evidence. Dr. Hughes has not personally engaged in any substantial analysis. Moreover, Defendants and Dr. Hughes ignore or mischaracterize essential legal concepts such as the distinction between injury and damages. Indeed, Dr. Hughes makes the outlandish claim that [redacted] despite both common sense and commonly accepted studies that if branded drug companies do not illegally game the system, generic drugs cost about 10% of their branded counterparts. But Warner Chilcott did game the system and Dr. Hughes gets to his

ridiculous conclusion by manipulating the data in an unorthodox way; a manipulation in which he was not directly involved.

Dr. Hughes' opinions are built upon economic, legal, and factual misrepresentations, not sound methodologies. While Dr. French has followed established methodologies for determining injury and damages in pharmaceutical monopolization litigation, Dr. Hughes presents *ipse dixit* rationalizations for arguments that belie common sense. Warner Chilcott spent millions of dollars and went to extraordinary efforts to protect its Loestrin 24 franchise from generic competition. Yet Dr. Hughes' primary opinion is that [redacted] – an opinion that is absurd and thoroughly contradicted by the weight of authority. To get there, Dr. Hughes misuses data regarding Warner Chilcott's marketing efforts and cherry picks other data. In Dr. Hughes' world, Warner Chilcott is some sort of charity, not a profit maximizing corporation which paid tens of millions of dollars to its competitors to stay out of its markets, and which sold Loestrin pills under the name Minastrin with instructions to chew rather than swallow the same pill in order to evade laws providing for automatic generic substitution. These are the same analyses that they claim Dr. French should have made.

Defendants take issue with Dr. French's analyses. But at the class certification stage, EPPs are only required to show that Dr. French has demonstrated a workable methodology. Dr. French's analysis goes well beyond this standard. It is Dr. Hughes' opinion, not Dr. French's, which is unreliable. Because Dr. Hughes' opinion is misleading and it is not helpful to the trier of fact, it should be excluded while Dr. French's opinion should be admitted as evidence.

II. BACKGROUND

A. Dr. French's June 30, 2018 Declaration

On July 30, 2018, Dr. French submitted the Expert Report of Gary L. French, Ph.D., Regarding Impact And Damages To End-Payor Plaintiffs ("French Rprt.") (attached to the

Declaration Of Michael M. Buchman, Esq. In Support Of End-Payor Plaintiffs' Motion For Class Certification And Appointment Of Class Counsel filed July 30, 2018, as Exh. 4). Dr. French has substantial expertise in this field. Dr. French received three degrees in the field of Economics from the University of Houston: a Bachelor of Business Administration degree in 1966, a Masters degree in 1971, and a Ph.D. in 1973. He served on the faculties of three universities, teaching economics and finance. For the past four decades, Dr. French has been affiliated with Nathan Associates, a global economic consulting firm. Appx. A to French Rprt. and French Rprt. ¶¶ 1-2.

Dr. French begins his analysis in his declaration with a detailed analysis of the pharmaceutical industry and the EPPs' claims in the case. He then conducts an analysis of evidence in the record employing principles of economics and concludes that there is class-wide evidence that could be used to demonstrate injury and damages to EPPs.

As Dr. French states,

[redacted]

French Rprt. ¶¶ 28-31.

Dr. French then explains how government and academic studies have repeatedly found:

[redacted]

French Rprt. ¶ 33, *see id.* ¶¶ 34-42.

Specifically addressing Loestrin, [redacted]

[redacted]

[redacted]

French Rprt. ¶ 43 (footnotes omitted).

Dr. French also demonstrated injury directly by analyzing data regarding actual sales of branded and generic Loestrin and Minastrin. As Dr. French summarizes:

[redacted]

French Rprt. ¶ 47.

[redacted] French Rprt. ¶¶ 49-52.

The injury to class members caused by Warner Chilcott illegally gaming the system is further demonstrated by the actual experience at generic entry of Minastrin, the chemically identical drug to which Warner Chilcott hopped Loestrin users. As Dr. French explains,

[redacted]

French Rprt. ¶ 55.

As Dr. French concludes, all class members were injured by paying artificially high prices caused by Warner Chilcott's monopolization:

[redacted]

French Rprt. ¶¶ 58-59.

In order to estimate aggregate damages, [redacted].[2] French Rprt. ¶ 60. [redacted]. *Id.* ¶¶ 66-67. [redacted]. *Id.* ¶¶ 71-74. [redacted]

[1] William H. Page, ed., Proving Antitrust Damages: Legal and Economic Issues, Section of Antitrust Law American Bar Association, (1996). p. 37; Robert E. Hall and Victoria A. Lazear, "Reference Guide on Estimation of Economic Losses in Damages Awards," Reference Manual on Scientific Evidence, 2nd ed. Federal Judicial Center (2000): 277-332. pp. 322-325.; Robert R. Bergstrom, "The Role of the Expert in Proving and Disproving Damages in Antitrust Claims," Antitrust Bulletin (1966): 9(4), 677-706.

[2] *Coastal Fuels of Puerto Rico, Inc. v. Caribbean Petroleum Corp.*, 175 F.3d 18, 25 at n. 3 (1st Cir. 1999) (recognizing the "before-and-after" and "yardstick" methods as "accepted methods of economics".)

[redacted].[3]

Dr. French estimates [redacted] in damages using the Loestrin experience, and [redacted] in damages using the Minastrin experience. French Rprt. ¶ 98 and Tables 5 and 6.

B. Dr. Hughes' October 19, 2018 Declaration

On October 19, 2018, Dr. Hughes submitted his report.[4] [redacted]

C. Dr. French's December 7, 2018 Reply Declaration

On December 7, 2018, Dr. French issued the Reply Report Of Gary L. French, Ph.D., Regarding Impact And Damages To End-Payor Plaintiffs ("French Reply Rprt.") (attached to the Declaration Of Marvin A. Miller In Support Of End-Payor Plaintiffs' Motion To Exclude The Testimony And Opinions Of James W. Hughes, Ph.D., And In Opposition To Defendants' Motion To Exclude The Testimony And Opinions Of Gary L. French, Ph.D. filed December 7,

[3] Although Warner Chilcott stopped selling Loestrin in July 2013, retail pharmacies continued to sell branded Loestrin which was already in the market.

[4] Dr. Hughes submitted a corrected report on November 12, 2018. All of the cites herein are to the corrected Hughes Report.

2018 ("Miller Dec." as Exhibit 1). In that declaration, Dr. French responds to criticisms Dr. Hughes made of his initial declaration, and demonstrates that all of these criticisms were unfounded. [redacted]. French Reply Rprt. ¶¶ 57-59.

Dr. French also updates his damages calculations. [redacted]. French Reply Rprt. ¶¶ 16-55. Dr. French also computes damages for the proposed TPP only alternative class, and finds those damages to be [redacted]. French Reply Rprt. ¶¶ 49-55.

Dr. French responds to Dr. Hughes' assertions concerning lack of injury, and demonstrates that all class members are injured. French Reply Rprt. ¶¶ 65-147.

III. STANDARDS FOR *DAUBERT* MOTIONS

Defendants fail to satisfy the relevant standard for excluding Dr. French's expert testimony. Federal Rule of Evidence 702 allows admission of expert opinions based on "scientific, technical, or other specialized knowledge" if such an opinion would "help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702. Under the *Daubert* standard, expert opinions are admissible if they are relevant and reliable. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993).

Expert opinion should only be excluded where it "is so fundamentally unsupported that it can offer no assistance to the jury." *United States v. Zolot*, 968 F. Supp. 2d 411, 417 (D. Mass. 2013) (quoting *In re Viagra Prods. Liab. Litig.*, 572 F. Supp. 2d 1071, 1078 (D. Minn. 2008)). Most criticisms of expert testimony should be addressed through the adversarial process, including

through cross-examination. *Id.* (adhering to "the Supreme Court's admonition that 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.'") (quoting *Daubert*, 509 U.S. at 596). The case law strongly favors allowing the jury to evaluate competing theories so long as they have an acceptable methodology and factual grounding. The only things that should be excluded are "junk science," a "junk scientist," or a "junk opinion." *Mass. Mut. Life Ins. Co. v. DB Structured Prods.*, No. 11-30039, 2015 WL 2130060, *829 (D. Mass. May 7, 2015) (citing *First Choice Armor & Equipment, Inc. v. Toyobo Am., Inc.*, 839 F. Supp. 2d 407, 416 (D. Mass. 2012)). The normal presumption is in favor of the admission of expert testimony: "under *Daubert*, 'the rejection of expert testimony is the exception rather than the rule.'" *In re: Welding Fume Products Liability Litig.*, No. 1:03–CV–17000, MDL 1535, 2005 WL 1868046, *5 (quoting the Advisory Committee Notes to Rule 702) (N.D. Ohio Aug. 8, 2005). "As long as an expert's scientific testimony rests upon 'good grounds, based on what is known,' *Daubert*, 509 U.S. at 590, 113 S.Ct. 2786 (internal quotation marks omitted), it should be tested by the adversary process—competing expert testimony and active cross-examination—rather than excluded from jurors' scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies, *see id.* at 596, 113 S.Ct. 2786." *Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co.*, 161 F.3d 77, 85 (1st Cir. 1998). "Admissibility under Rule 702 does not require perfect methodology." *Best v. Lowe's Home Centers, Inc.*, 563 F.3d 171, 181 (6th Cir. 2009). Moreover, "Rule 702 does not require an expert to have absolute certainty in formulating his opinion." *Dilts v. United Group Services, LLC*, 500 Fed.Appx. 440, 445, 2012 WL 4069576, *5 (6th Cir. 2012). "When the methodology is sound, and the evidence relied upon sufficiently related to the case at hand, disputes about the degree of relevance or accuracy (above this minimum threshold) may go to the testimony's weight, but not its admissibility." *United Food & Commercial Workers Local*

1776 v. Teikoku Pharma USA (In re Lidoderm Antitrust Litigation), No. 14-2521, 296 F. Supp. 3d 1142, 1177 (N.D. Cal. 2017), quoting *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 852 (Fed. Cir. 2010). Also, "*Daubert* does not require that a party who proffers expert testimony carry the burden of proving to the judge that the expert's assessment of the situation is correct." *Milward v. Acuity Specialty Prods. Grp.*, 639 F.3d 11, 15 (1st Cir. 2011).

In contrast, misleading analyses, such as in Dr. Hughes' Report, are not helpful to the trier of fact and should be excluded. For example, Dr. Hughes' analysis of free samples lacks any scientific methodology, and it substantially drives a number of his other analyses. As explained herein, Dr. Hughes' opinions are unreliable and misleading, and should therefore be excluded because they are not helpful to the trier of fact.

IV. ARGUMENT

A. Dr. French's Analysis Is Reliable and Admissible, While Dr. Hughes' Is Misleading and Should Be Excluded

1. Dr. French Is Only Trying to Demonstrate A Workable Methodology, Not a Final Result

At this stage of the litigation, Plaintiffs do not need to actually prove injury and damages; rather, they need only demonstrate that they have workable methodologies for proving injury and damages. *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 311-12 (3d Cir. 2008). The inquiry into the expert's methodology at the class certification stage is limited. The question "is whether the plaintiffs have established a *workable* multiple regression equation, not whether plaintiff's model *actually works*." *In re Titanium Dioxide Antitrust Litig.*, 284 F.R.D. 328, 347 (D. Md. 2012) (quoting *In re EPDM Antitrust Litig.*, 256 F.R.D. 82, 100 (D. Conn. 2009) (emphasis added)); *see also In re Amaranth Natural Gas Commodities Litig.*, 269 F.R.D. 366, 386, n. 118 (S.D.N.Y. 2010) (same)). Thus, "the issue at class certification is not which expert is the most credible, or the most accurate modeler, but rather have the plaintiffs demonstrated that there is

a way to prove a class-wide measure of [impact] through generalized proof." *Titanium Dioxide*, 284 F.R.D. at 347 (quoting *EPDM*, 256 F.R.D. at 100) (footnote omitted); *see also In re Ready-Mixed Concrete Antitrust Litig.*, 261 F.R.D. at 170.

2. Many of Defendants' Arguments Confuse Fact of Injury With Amount of Damages

Throughout Defendants' memorandum, and throughout Dr. Hughes' opinions, establishing fact of injury is confused with establishing amount of damages. In antitrust cases such as this one, these are different concepts, with different standards of proof.

EPPs need only demonstrate their expert's model can show *some* impact to establish fact-of-injury, *not the same* impact on each class member. *See, e.g., In re Potash Antitrust Litig.*, 159 F.R.D. 682, 694, 695 n.16, 696 (D. Minn. 1995). Dr. French's declarations do just that.

Moreover, while measuring the amount of damages is related to proving injury, or fact of damage, it is a distinct inquiry, with a different standard of ultimate proof. Once impact is demonstrated by a preponderance of the evidence, damages may be established by a reasonable estimate at a later stage. "No precise damage formula is needed at the certification stage of an antitrust action; the court's inquiry is limited to whether the proposed methods are so unsubstantial as to amount to no method at all." *In re Pressure Sensitive Labelstock Antitrust Litig.*, No. 3:03-MDL-1556, 2007 WL 4150666, at *19 (M.D. Pa. Nov. 19, 2007) (citation and alteration omitted); *accord In re Wellbutrin SR Direct Purchaser Antitrust Litig.*, No. 04-5525, 2008 WL 1946848, at *9 (E.D. Pa. 2008). This is due, in part, to the longstanding antitrust rule that "a defendant whose wrongful conduct has rendered difficult the ascertainment of the precise damages suffered by the plaintiff is not entitled to complain that they cannot be measured with the same exactness and precision as would otherwise be possible." *Eastman Kodak Co. of New York v. Southern Photo Materials Co.*, 273 U.S. 359, 379 (1927). "Any other rule . . . would be an inducement to make wrongdoing so effective and complete in every case as to preclude any

recovery, by rendering the measure of damages uncertain. Failure to apply it would mean that the more grievous the wrong done, the less likelihood there would be of a recovery." *Bigelow v. RKO Radio Pictures, Inc.*, 327 U.S. 251, 264-65 (1946). Because "the wrongdoer must bear the risks of the uncertainty which [its] conduct has created . . . it is hornbook law that doubts as to the certainty of damages will be resolved against the wrongdoer[.]" *In re Sumitomo Copper Litig.*, 182 F.R.D. 85, 92-93 (S.D.N.Y. 1998) (internal quotation marks and citation omitted). For instance, in *SRAM*, the court determined that it was appropriate for the plaintiffs to use averages to estimate the extent to which monopoly prices were passed on to indirect purchasers:

> The question of what would have happened but for Microsoft's monopoly overcharge is a hypothetical, and a hypothetical question generally cannot be answered by historical data about what actually happened, but must often be answered by general principles about what generally tends to happen. Thus, average pass through rates appear reasonable and even necessary to prove damages here.

In re Static Random Access Memory (SRAM) Antitrust Litig., 264 F.R.D. 603, 614 (N.D. CA 2009) (quoting *Gordon v. Microsoft Corp.*, No. MC 00-5994, 2003 WL 23105550, at *3 (D. Minn. Dec. 15, 2003).

3. Dr. French Relies Upon Standard Methodologies to Establish Injury

Dr. French establishes, through his examination of the economic literature, the facts of the case, and the data he analyzed, that all class members were injured. French Rprt. ¶¶33-98. The effects of generic competition on pharmaceutical prices are well-studied and largely beyond dispute. Generics quickly capture the vast majority of brand sales at lower prices, and generic prices fall as the number of generic competitors increases and generic competition proceeds. French Rprt. ¶¶ 33-42; *see, e.g.*, ECF No. 518-5, Federal Trade Commission Staff Study, Pay-For-Delay: How Drug Company Pay-Offs Cost Consumers Billions at 8 (Jan. 2010) (concluding that one year following initial entry, generics took 90% of brand sales and generic prices were 85% lower than pre-entry branded prices). As a result, conduct that delays and suppresses generic

competition predictably inflicts overcharges on indirect purchasers. French Rprt. ¶¶20-32. Plaintiffs allege that Defendants' conduct impaired generic competition, and further, that with unimpaired generic competition, Class members would have paid less because they would have substituted less-expensive generic Loestrin for more-expensive brand Loestrin and/or Minastrin, and/or because they would have paid less for the generic Loestrin and/or generic Minastrin that they did purchase.

Dr. French concluded that, assuming Defendants are found to have impaired generic competition as Plaintiffs allege, there is evidence and analysis, common to the Class as a whole, that the impaired generic competition resulted in class-wide antitrust impact in the form of overcharges, the appropriate measure of damages in this type of antitrust case.

The evidence Dr. French analyzed to reach that conclusion included, among other things: (i) economic and governmental studies showing the dramatic price-reducing effects of generic competition; (ii) Warner Chilcott's own forecasts and executive testimony predicting significant generic penetration and substantially lower prices once generic Loestrin entered the market; and (iii) computerized sales data from IQVIA showing the significant market-wide effects of generic competition in this case. French Rprt. ¶¶ 33-57, 95. "[T]hese are precisely the types of evidence that have been found sufficient to satisfy the predominance requirement with respect to proof of impact in other cases alleging delayed generic entry." *Meijer, Inc. v. Warner Chilcott Holdings Co. III, Ltd.*, 246 F.R.D. 293, 309 (D.D.C. 2007). *See also, e.g., In re Lidoderm Antitrust Litig.*, No. 14-md-02521-WHO, 2017 WL 679367, at *9-10 (N.D. Cal. Feb. 21, 2017); In re *Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 14-md-02503, 2017 WL 4621777, at *7-8 (D. Mass. Oct. 16, 2017); *In re Relafen Antitrust Litig.*, 218 F.R.D. 337, 343-44 (D. Mass. 2003).

Defendants' employ Dr. Hughes' unreliable and misleading methodologies as their basis for criticism that Dr. French should have conducted some sort of individual inquiry regarding

the individual facts of each and every class member to find injury. Such inquiry defeats the purpose of class actions and is not required.

4. Dr. Hughes' Analyses Adjusting Dr. French's Calculations based upon Coupons, Rebates, and Alternative Comparison Dates Should Be Excluded

a. Dr. Hughes' Adjustments for Free Samples Are Unreliable And Should Be Excluded

Dr. Hughes primary data distortion is his use of samples. Warner Chilcott extensively [redacted].[5] Warner Chilcott sold Loestrin at a price [redacted].[6] By providing [redacted] sample packages, Warner Chilcott hoped that doctors would give Loestrin to their patients to try, and that the samples would lead to actual paid sales.

Dr. Hughes, without any authority,[7] [redacted]. French Rprt. ¶¶ 46-47; *see id.* ¶¶14, fn.22, 48, 59, 98-99, 132, 134.

Warner Chilcott did not reduce the price of the pills by [redacted]. Warner Chilcott still sold Loestrin at a *supra*-competitive price throughout the class period. Each purchase of Loestrin was made at a price that causes injury.

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[5] James W. Hughes Deposition ("Hughes Dep.") 47:2-7 ("[redacted]"). A copy of the Hughes Deposition is attached to the Miller Declaration as Exhibit 2.

[6] John Goll Deposition 315:5-16 ([redacted]). A copy of the Goll Deposition is attached to the Miller Declaration as Exhibit 3.

[7] Hughes Dep. 68:16-21 (" Q [redacted] "); *see also id.* at 67:18-68:14.

Dr. Hughes admitted [redacted]. Hughes Dep. 47:2-7. There is no support in the literature or law for reducing injury or damages by the amount of [redacted]. Hughes Dep. 67:18-68:21. While he sarcastically said that [redacted] it is not. Hughes is improperly turning [redacted] Indeed, given the inability to track the ultimate use or non-use of samples, it is clear that if reducing prices had been a goal, it would have been more effective to directly lower price.

Indeed, Dr. Hughes is effectively suggesting that Warner Chilcott was intentionally cannibalizing its paid sales and profits through the samples. It was doing nothing of the sort. Its documents show that it [redacted].[8]

Moreover, even if Dr. Hughes' claims had any validity, his methodology is further flawed by how he implements it. Dr. Hughes [redacted]

[8] Hughes Dep. at 63:5-21; 69:10-23.

[9] Hughes Dep. 43:18-21 ("[redacted]").

[redacted].[10] Dr. Hughes does not know:

-- [redacted];[11]

-- [redacted];[12]

-- [redacted][13]

-- [redacted];[14] or

-- [redacted].[15]

Dr. Hughes blithely ignores these realities and [redacted]

[redacted]

[10] Sumanth Addanki Deposition 84:6-11 [redacted]. A copy of the Addanki Deposition is attached to the Miller Declaration as Exhibit 4.

[11] Hughes Dep. 61:10-13 [redacted]

[12] Hughes Dep. 67:14-17 [redacted] *see* Westfall, McCabe, and Nicholas, Personal Use of Drug Samples by Physicians and Office Staff, JAMA Vol. 278 No. 2 at 141-43 (July 9, 1997) (doctors and their office staff use free samples); Morelli and Koenigsberg, Sample medication dispensing in a residency practice, Journal of Family Practice (Jan. 1992) at p. 42 et seq., found at https://go.galegroup.com/ps/i.do?p=AONE&sw=w&u=googlescholar&v=2.1&it=r&id=GALE|A11986479&sid=classroomWidget&asid=9f75057e (last visited Oct. 31, 2018) (attached to the Miller Declaration as Exhibit 6) (doctors and their office staff use free samples).

[13] Hughes Dep. 69:10-14 [redacted]

[14] Hughes Dep. 71:5-72:12 [redacted].

[15] Hughes Dep. 58:19-59:12 ([redacted].

[redacted]

[redacted].

b. Dr. Hughes' Adjustments for Co-Pay Coupons Are Unreliable And Should Be Excluded

Dr. Hughes also ignores the very reason Warner Chilcott distributed co-pay coupons when opining that [redacted].

Most prescription drug insurance plans make use of a formulary to reduce costs to the plan sponsor. A formulary is a list of drugs listed by their preference to the plan sponsor.[16] Typically a formulary will have three tiers, with the cheapest drugs, which are generally generics, on the first tier with the lowest patient co-pay. The second tier will have costlier drugs and a higher patient co-pay. The third tier is generally populated with the costliest branded drugs, and it will have the highest co-pay.[17] Prescription drug plans use the formulary and varying co-pays to steer patients towards using the least costly drugs by having lower co-pays on them.

Some pharmaceutical manufacturers will pay rebates to plans to lower the price of their drugs to the plan in return for more favorable formulary placement, *i.e.*, placing the drug on tier 2 instead of tier 3. [redacted].[18] [redacted] Thus, Loestrin could be a tier 3 drug with a high co-pay, but the co-pay coupon could reduce the patient's out of pocket cost at the pharmacy, thus lowering the patient's resistance to the higher co-pay. [redacted][19] Indeed, by defeating the tiered nature of

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[16] Hughes Dep. 79:1-10.

[17] Hughes Dep. 85:17-86:9; *see* Hughes Rprt. at Ex. 11.A. Some plans may also refuse to cover some branded drugs, leaving the entire cost of them to the patient. *See* Hughes Dep. 85:2-12.

[18] Hughes Dep. 86:21-87:13.

[19] Hughes Dep. 87:14-89:5.

the formulary, co-pay coupons hurt plan sponsors by encouraging patients to use drugs that cost the plans more than other drugs.

It is unreliable for Dr. Hughes to look at co-pay coupons [redacted]. The price that the pharmacy charges is the same with or without the coupon. While the patient may sometimes reduce or escape injury by using the co-pay coupon, the TPP's injury is unaffected.

c. Dr. Hughes' Adjustments for the Price Comparison Date Are Unreliable And Should Be Excluded

Generic manufacturers set their prices in comparison to the branded drug's price on the date of generic entry. Here, Dr. French did that. French Report at ¶ 77. But since Warner Chilcott had already withdrawn Loestrin from the market as part of its illegal scheme, Dr. Hughes [redacted].

Dr. Hughes has no support for [redacted] than his own *ipse dixit*. Drug prices rise over time, as has been the case with Loestrin. Had Warner Chilcott not withdrawn Loestrin from the market, there is no reason to think Warner Chilcott would not have continued to raise the price of Loestrin in order to maximize the profits from sales to brand loyalists.

d. Dr. Hughes' Adjustments for the Generic Penetration Rate Are Unreliable and Should Be Excluded

The established literature shows that the typical generic penetration rate is [redacted]. French Report at ¶ 37.

Dr. Hughes, however, claims that the generic penetration rate should instead be modeled [redacted]. Dr. Hughes has no reason to do this because [redacted].[20] The result was a staggered series of generic entries unlike the norm.

[20] Bayer 2011 Annual Report at 257-58 (attached to the Miller Declaration as Exhibit 7).

5. Dr. French Was Not Required To Ascertain The Actual Identities of Class Members, And Dr. Hughes' Opinions To The Contrary Should Be Excluded

Dr. Hughes repeatedly faults Dr. French for failing to ascertain the actual identities of absent class members. In doing so, Dr. Hughes is giving unreliable opinions because they misrepresent the law, and they should be excluded.

Despite Defendants' claims that *In re Asacol Antitrust Litigation*, 907 F.3d 42 (1st Cir. 2018), requires Dr. French to ascertain the actual identities of class members in advance of a damages verdict, there is no requirement that he do so. In *Asacol*, the First Circuit was confronted with a case where the plaintiff class *definition* included approximately 10% uninjured brand loyal members. Plaintiffs there proposed using affidavits *before the trial* to exclude the uninjured consumers. The First Circuit found that because the affidavits were inadmissible at trial, they could not be used to cull the class. In contrast, in this case brand loyalists have been explicitly excluded from the class definition. *Asacol* at no point states that aggregate damages verdicts are inappropriate. *See also Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036 (2016) (affirming aggregate damages verdict).

Defendants' *Asacol* argument deliberately confuses two different concepts: whether a class definition has been properly drawn to exclude uninjured members, and whether the actual identities of class members must be known by name before trial. These two concepts are sometimes referred to as ascertainability. *Asacol* does not discuss acertainability: the word does not appear in the opinion. The conventional view is that so long as the class uses objective criteria to define who is a member, it is proper. *Matamoros v. Starbucks Corp.*, 699 F.3d 129, 139 (1st Cir. 2012). The flaw with the class definition in *Asacol* was that it was overbroad in that it did not contain sufficient objective criteria to exclude uninjured parties from falling within it. The First Circuit has not adopted what is sometimes referred to as a heightened ascertainability

requirement which defendants often argue to require that the actual names of class members can be determined before trial.[21] Indeed, imposing such a requirement is antithetical to the class action device of Rule 23.

Dr. Hughes' analysis is deeply flawed and uses an unreliable methodology. [redacted]

6. PBMs Are Not Class Members

Dr. Hughes raises the hypothetical possibility [redacted]. Hughes Rprt. ¶ 56; Hughes Dep. 168:25-172:5.

[21] While the Third Circuit has moved toward such a requirement, *see, e.g.*, *Byrd v. Aaron's Inc.*, 784 F.3d 154 (3d Cir. 2015), other circuits have explicitly rejected such a requirement. *Mullins v. Direct Digital, LLC*, 795 F.3d 654 (7th Cir. 2015). The recent opinion in *In re Thalomid and Revlimid Antitrust Litig.*, No. 14-6997, 2018 WL 5984916 (D.N.J. Oct. 30, 2018), states that even in the Third Circuit, "[a]scertainability does not . . . require plaintiff to identify all class members at class certification." *Id.* Unlike here, the *Thalomid* class definition did not exclude brand loyal consumers. While its findings with respect to consumer class members was mixed, *Thalomid* found that there was sufficient evidence that TPPs were injured and were ascertainable under Third Circuit standards. The court denied class certification without prejudice so that the EPPs could further address the issues as to consumers.

[22] To the extent it may be appropriate to tweak the class definition to improve its exclusion of uninjured parties, such tweaking is preferable to a wholesale denial of class certification. *See In re Urethane Antitrust Litig.*, 2013 WL 2097346, *2 (D. Kan. 2013).

Make no mistake: it does not happen. As Myron Winkelman's opinion makes clear, [redacted] [redacted].[23] Winkelman Rep. ¶¶ 45-56.

To the extent that PBMs pass along rebates to plan sponsors, it happens months after purchases. Generally, the rebate is in the form of a single lump sum check for a multitude of drugs and drug purchases. PBMs do not itemize rebates. *See, e.g.*, [redacted]

Moreover, PBMs often pocket rebates. For example, [redacted]

However, to avoid any further confusion, EPPs are amending the class definition to explicitly exclude PBMs.

7. Dr. Hughes' Analyses Purporting to Show Lack Of Injury Are Unreliable, And Should Be Excluded

[redacted]

a. All TPPs Were Injured

[redacted]

[23] So that there is no confusion, EPPs seek to have the Court certify a class that explicitly excludes PBMs.

[24] [redacted]

The adjustments for free samples is inappropriate, as discussed above. [redacted] Exhibits 14, 15.A, and 15.B, also are flawed because [redacted]. *See* Note 2 to Exhibits 14, 15.A, and 15.B. In addition, [redacted]. *See* Hughes Dep.132:7-134:8. [redacted]. French Reply Rprt. ¶¶ 100-09.

Dr. Hughes also ignores [redacted] Not only is this contrary to law, it shows a fundamental misunderstanding of premiums. Premiums are not fluid; to the extent they can be changed, they are set partially in accordance with the prior year's experience. Thus, when Warner Chilcott increases the price of Loestrin, a plan sponsor cannot charge Loestrin users more that month. *See, e.g.*, *In re Terazosin Hydrochloride Antitrust Litig.*, 220 F.R.D. 672, 690 (S.D. Fla. 2004) ("Further, to the extent that any third-party payor did charge its insureds a higher premium because of a drug company's monopolistic activities, the charging of a higher premium in the future cannot be accurately described as a "pass on" of those charges."); *In re Asacol Antitrust Litig.*, No. 15-cv-12730, 2017 WL 53695, *4 (D. Mass. Jan. 4, 2017) ("'[I]nsurance premiums are not a 'pass on' of alleged overcharges because premiums are set by anticipating future projected costs, not to recover money that insurers paid in the past.'") (quoting *In re Solodyn Antitrust Litig.*, MDL No. 14-2503, 2016 WL 6897809, *2 (D. Mass. Sept. 19, 2016)); *In re Pharmaceutical Industry Average Wholesale Price Litig.*, 491 F. Supp.2d 20, 96-97 (D. Mass. 2007).

b. All Consumers Within The Class Definition Were Injured

Dr. Hughes also [redacted] While Plaintiffs' class definition excludes brand loyal consumers, Dr. Hughes [redacted]

8. Dr. French Is Not Required To Accept Warner Chilcott's Self-Serving Defenses

Warner Chilcott contends that Dr. French should be faulted for not accepting that if it had not engaged in the illegal conduct alleged by EPPs in this case, including the "hard hop" from branded Loestrin to branded Minastrin in 2013, Warner Chilcott would have instead introduced branded Minastrin in 2009. This is not what Warner Chilcott did, and Dr. French is not required to use it for a but-for world. At most, this is a subject about which Defendants can cross-examine Dr. French.[25]

As Dr. French has opined, [redacted]. French Reply Rep. ¶¶ 78-81. Minastrin is chemically the same as Loestrin. However, by adding an instruction to chew it when seeking FDA approval and by adding a mint flavor to make it more palatable, the FDA would not allow automatic generic substitution of generic Loestrin for a prescription written for branded Minastrin.

Defendants are not permitted to limit Plaintiffs' damages by speculating that Plaintiffs may have suffered the same harm if they were only subject to conduct that complied with the

[25] *Packgen v. Berry Plastics Corp*, 46 F. Supp. 3d 92,110–11 (D. Maine 2014) ("Berry has the right to challenge the assumptions that Mr.Filler has drawn from such information, but the evidence in support of its position goes to the weight and credibility of Mr. Filler's expert opinion, not its admissibility.").

antitrust laws.[26] Thus, Defendants cannot seek to mitigate the harm they caused to the Class by arguing that if they had not executed their anticompetitive scheme by delaying competition, depriving the market of an authorized generic, and withdrawing Loestrin 24, they would have instead acted competitively (or less anti-competitively) by introducing Minastrin 24 prior to generic entry. Defendants' effort to argue exactly that must be rejected.

Experts are not required to assume Defendants' speculative explanations of contested evidence, and Dr. French's opinions are reliable.

9. Dr. French Has Now Added The Rebate Data That Defendants Claim He Should Have Used His Analysis, And Defendants Helped Cause This Issue

While Defendants criticize Dr. French for not using certain [redacted] they fail to mention that Defendants refused to respond to a request that they explain what that entry meant in supposed [redacted] In any event the adjustment is minimal, and has been made in his Reply Report.

[26] *See Story Parchment Co. v. Paterson Parchment Paper Co.*, 282 U.S. 555, 561-68 (1931) (allowing plaintiff to seek damages on entire price difference even though defendants claimed that they could have lowered prices anyway for lawful reasons); *Virginia Vermiculite, Ltd. v. W.R. Grace & Co.*, 156 F.3d 535, 540 (4th Cir. 1998) ("even if Grace lawfully could have donated the lands to HGSI without the nonmining agreements, it is foreclosed from challenging causation simply on the basis that it could have achieved the same result through lawful means"); *Irvin Indus., Inc. v. Goodyear Aerospace Corp.*, 974 F.2d 241, 245 (2d Cir. 1992) ("The possibility that [defendant] might have submitted a lawful bid, and, if so, the same damage might have resulted, cannot in and of itself negate causation as a matter of law"); *Lee-Moore Oil Co. v. Union Oil Co.*, 599 F.2d 1299, 1302 (4th Cir. 1979) ("the fact that [the defendant] might have caused the same damages by a lawful cancellation of the contract is irrelevant"); *H.J., Inc. v. ITT Corp.*, 867 F.2d 1531, 1550 (8th Cir. 1989); *In re Skelaxin (Metaxalone) Antitrust Litig.*, No. 1:12-md-2343, 2014 WL 2002887, at *5 (E.D. Tenn. May 15, 2014) ("[J]uries will not be forced down the rabbit hole of hypothetical issues antitrust violators may raise to minimize their liability."); *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 648, fn. 16 (E.D. Mich. 2000) ("[t]o accept Defendants' argument, the Court must also accept the argument that there can never be an antitrust violation if the antitrust defendant can posit an argument that it could have lawfully done the same thing it is accused of doing collusively. The Court finds these arguments unavailing."), *aff'd*, 332 F.3d 896 (6th Cir. 2003).

Dr. French [redacted]. French Dep. at 261:10-269:6; Hughes Dep. at 101:24–108:12; Hughes Dep. Ex. 4 and 5 (attached to the Miller Declaration as Exhibits 10 and 11). Dr. Hughes also [redacted] Hughes Rprt. ¶ 110.

Defendants were previously asked what [redacted] meant in the [redacted]. Defendants refused to answer. *See* Letter dated Nov. 3, 2017 from Lauren Papenhausen to Daniel J. Walker at pages 16-17, response to question 36 (attached to the Miller Declaration as Exhibit 12).

While Dr. French can hardly be faulted for this alleged oversight, in his Reply Report, he has assumed these entries to be [redacted] as Defendants contend, and accounts for them. Their effect on his analysis was not significant.

10. Dr. Hughes Is Serving As A Mouthpiece For Unknown Analysts Who Cannot Be Cross Examined

Dr. Hughes's testimony is also inadmissible because he simply parrots the conclusions of unknown analysts as opposed to conducing an independent analysis of his own. Courts uniformly and routinely exclude testimony "when an expert is 'just parroting the opinion of another expert.'" *U.S. Gypsum Co. v. Lafarge N. Am. Inc.*, 670 F. Supp. 2d 748, 758 (N.D. Ill. 2009) (*quoting Dura Auto. Sys. Of Ind., Inc. v. CTS Corp.*, 285 F.3d 609, 613 (7th Cir. 2002)) (internal quotation marks omitted). An expert may not "merely serve as a spokesman for the absent expert, vouching for the truth of his statements." *Id.* (citing *In re James Wilson Assocs.*, 965 F.2d 160, 172–73 (7th Cir. 1992)). While "experts are permitted to rely on opinions of other experts . . . in doing so, the

expert witness must in the end be giving his *own* opinion. He cannot simply be the conduit for the opinion of an unproduced expert." *Malletier v. Dooney & Bourke, Inc.*, 525 F. Supp. 2d 558, 664 (S.D.N.Y. 2007).

Here, Dr. Hughes indicated that he did not direct and does not know much about the free sample analysis which drives many of his opinions. As Dr. Hughes stated, [redacted]. Hughes Dep. 73:1-9 (emphasis added). [redacted] Hughes Dep. 54:5-17 (emphasis added). [redacted]. Hughes Dep. 54:8-55:9; 56:18-57:11; 73:3-75:14. Instead, he merely accepts the sample analysis performed by others.

While a testifying expert can have staff assist him, he cannot present analyses that he did not direct and did not perform as his own. The critical question therefore is whether the expert "independently evaluated or verified the opinions upon which he relies." *Hunt v. McNeil Consumer Healthcare*, 297 F.R.D. 268, 275 (E.D. La. 2014). *See Thorndike v. DaimlerChrysler Corp.*, 266 F. Supp. 2d 172, 185 (D. Maine 2003). Reports like these shield the true expert from cross

examination before the jury, leaving the expert analysis effectively untested. *See Matter of James Wilson Assocs.*, 965 F.2d at 172–73.

V. CONCLUSION

For the foregoing reasons, EPPs respectfully request that the Court deny Defendants' motion to exclude Dr. French's opinions, and grant their motion to exclude Dr. Hughes' opinions.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on December 14, 2018, a true copy of the foregoing document was served on all counsel of record by electronically filing the document with the Court's CM/ECF system.

/s/ Michael M. Buchman
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